

UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
FORT MYERS DIVISION

UNITED STATES OF AMERICA,

Plaintiff,

v.

Case No.: 2:23-cv-475-SPC-KCD

MICHAEL J. CONNORS,
PROTOUCH MARKETING, LLC,
WOODFORD HILLS, LLC,
OAKHILL RESEARCH, LLC,
EVERGREEN MARKETING, LLC,
STERLING HEALTH, LLC and
CLARA VISTA MEDIA, LLC,

Defendants.

**PERMANENT INJUNCTION, MONETARY JUDGMENT, CIVIL
PENALTY JUDGMENT, AND OTHER RELIEF**

Plaintiff, the United States of America, acting upon notification and authorization to the Attorney General by the Federal Trade Commission (“Commission” or “FTC”), filed its Complaint for Permanent Injunction, Monetary Relief, Civil Penalties, and Other Relief (“Complaint”), for permanent injunctive relief, monetary relief, civil penalties, and other relief in this matter, pursuant to Sections 5(a)(1), 5(m)(1)(A), 12, 13(b), 16(a), and 19 of the Federal Trade Commission Act (“FTC Act”), 15 U.S.C. §§ 45(a)(1), 45(m)(1)(A), 52, 53(b), 56(a), and 57b; and Section 8023 of the Opioid Addiction Recovery Fraud Prevention Act of 2018 (“OARFPA”), 15 U.S.C. § 45d.

Defendants waived service of the summons and the Complaint. Plaintiff and Defendants stipulate to the entry of this Order for Permanent Injunction, Monetary Judgment, Civil Penalty Judgment, and Other Relief (“Order”) to resolve all matters in dispute in this action between them.

Accordingly it is now

ORDERED:

FINDINGS

1. This Court has jurisdiction over this matter.
2. The Complaint charges that Defendants participated in deceptive acts or practices in violation of Sections 5 and 12 of the FTC Act, 15 U.S.C. §§ 45, 52, and Section 8023 of OARFPA, 15 U.S.C. § 45d, in the advertising, marketing, promotion, offering for sale, sale, and distribution of Smoke Away-branded products as effective smoking cessation products that eliminate nicotine cravings and withdrawal symptoms.
3. Defendants admit the allegations in the Complaint.
4. Defendants waive any claim that they may have under the Equal Access to Justice Act, 28 U.S.C. § 2412, concerning the prosecution of this action through the date of this Order, and agree to bear their own costs and attorney fees.
5. Defendants and Plaintiff waive all rights to appeal or otherwise challenge or contest the validity of this Order.

DEFINITIONS

For the purpose of this Order, the following definitions apply:

A. **“Covered Product”** means any Dietary Supplement, Food, or Drug.

B. **“Defendants”** means all Individual Defendant and Corporate Defendants, individually, collectively, or in any combination.

1. **“Corporate Defendants”** means ProTouch Marketing, LLC, also doing business as Smart Day Supplements; Woodford Hills, LLC; Oakhill Research, LLC; Evergreen Marketing, LLC; Sterling Health, LLC; Clara Vista Media, LLC; and their successors and assigns.

2. **“Individual Defendant”** means Michael J. Connors.

C. **“Dietary Supplement”** means: (1) any product labeled as a dietary supplement or otherwise represented as a dietary supplement; or (2) any pill, tablet, capsule, powder, softgel, gelcap, liquid, or other similar form containing one or more ingredients that are a vitamin, mineral, herb or other botanical, amino acid, probiotic, or other dietary substance for use by humans to supplement the diet by increasing the total dietary intake, or a concentrate, metabolite, constituent, extract, or combination of any ingredient described above, that is intended to be ingested, and is not represented to be used as a conventional food or as a sole item of a meal or the diet.

D. **“Drug”** means: (1) articles recognized in the official United States Pharmacopoeia, official Homoeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; (2) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans or other animals; (3) articles (other than food) intended to affect the structure or any function of the body of humans or other animals; and (4) articles intended for use as a component of any article specified in (1), (2), or (3); but does not include devices or their components, parts, or accessories.

E. **“Essentially Equivalent Product”** means a product that contains the identical ingredients, except for inactive ingredients (e.g., binders, colors, fillers, excipients) in the same form and dosage, and with the same route of administration (e.g., orally, sublingually), as the Covered Product; provided that the Covered Product may contain additional ingredients if reliable scientific evidence generally accepted by experts in the field indicates that the amount and combination of additional ingredients is unlikely to impede or inhibit the effectiveness of the ingredients in the Essentially Equivalent Product.

F. **“Food”** means: (1) any article used for food or drink for humans or other animals; (2) chewing gum; and (3) any article used for components of any such article.

ORDER

I. BAN ON SUBSTANCE USE DISORDER TREATMENT PRODUCTS OR SERVICES

It is ordered that Defendants are permanently restrained and enjoined from engaging, participating, or assisting, in any manner or in any capacity whatsoever, in the advertising, marketing, promoting, offering for sale, selling, or distribution of any substance use disorder treatment product or service, including any smoking cessation product or service.

For purposes of this Section, “substance use disorder treatment product or service” means (1) any product for use or marketed for use in the treatment, cure, or prevention of a substance use disorder; or (2) any service that purports to provide referrals to treatment, treatment, or recovery housing for people diagnosed with, having, or purporting to have a substance use disorder.

For purposes of this Section, “smoking cessation product or service” means any product or service that is advertised, marketed, promoted, offered for sale, sold, or distributed for quitting smoking, eliminating or reducing the use of cigarettes, or eliminating or reducing nicotine dependency, cravings, or withdrawal symptoms.

II. PROHIBITED REPRESENTATIONS: HEALTH-RELATED CLAIMS REQUIRING HUMAN CLINICAL TESTING FOR SUBSTANTIATION

It is further ordered that Defendants, Defendants' officers, agents, employees, and attorneys, and all other persons in active concert or participation with any of them, who receive actual notice of this Order, whether acting directly or indirectly, in connection with the advertising, marketing, promotion, offering for sale, sale, or distribution of any Covered Product not covered under the Section of this Order entitled Ban on Substance Use Disorder Treatment Products or Services, are permanently restrained and enjoined from making, or assisting others in making, expressly or by implication, including through the use of a product or program name, endorsement, depiction, or illustration, any representation that such product:

- A. cures, mitigates, or treats any substance use disorder or symptom of a substance use disorder; or
- B. cures, mitigates, or treats any disease

unless the representation is non-misleading, and, at the time of making such representation, they possess and rely upon competent and reliable scientific evidence substantiating that the representation is true. For purposes of this Section, competent and reliable scientific evidence must consist of human clinical testing of the Covered Product, or of an Essentially Equivalent Product, that is sufficient in quality and quantity based on standards generally accepted

by experts in the relevant disease, condition, or function to which the representation relates, when considered in light of the entire body of relevant and reliable scientific evidence, to substantiate that the representation is true. Such testing must be: (1) randomized, double-blind, and placebo controlled; and (2) conducted by researchers qualified by training and experience to conduct such testing. In addition, all underlying or supporting data and documents generally accepted by experts in the field as relevant to an assessment of such testing as described in the Section entitled Preservation of Records Relating to Competent and Reliable Human Clinical Tests or Studies must be available for inspection and production to the Commission. Persons covered by this Section have the burden of proving that a product satisfies the definition of Essentially Equivalent Product.

III. PROHIBITED REPRESENTATIONS: OTHER HEALTH-RELATED CLAIMS

It is further ordered that Defendants, Defendants' officers, agents, employees, and attorneys, and all other persons in active concert or participation with any of them, who receive actual notice of this Order, whether acting directly or indirectly, in connection with the advertising, marketing, promotion, offering for sale, sale, or distribution of any Covered Product not covered under the Section of this Order entitled Ban on Substance Use Disorder Treatment Products or Services, are permanently restrained and enjoined from making, or assisting others in making, expressly or by

implication, including through the use of a product or program name, endorsement, depiction, or illustration, any representation, other than representations covered under the Section of this Order entitled Prohibited Representations: Health-Related Claims Requiring Human Clinical Testing For Substantiation, about the efficacy of any Covered Product, unless the representation is non-misleading, and, at the time of making such representation, they possess and rely upon competent and reliable scientific evidence that is sufficient in quality and quantity based on standards generally accepted by experts in the relevant disease, condition, or function to which the representation relates, when considered in light of the entire body of relevant and reliable scientific evidence, to substantiate that the representation is true.

For purposes of this Section, competent and reliable scientific evidence means tests, analyses, research, or studies (1) that have been conducted and evaluated in an objective manner by experts in the relevant disease, condition, or function to which the representation relates; (2) that are generally accepted by such experts to yield accurate and reliable results; and (3) that are randomized, double-blind, and placebo-controlled human clinical testing of the Covered Product, or of an Essentially Equivalent Product, when such experts would generally require such human clinical testing to substantiate that the representation is true. In addition, when such tests or studies are human clinical tests or studies, all underlying or supporting data and documents

generally accepted by experts in the field as relevant to an assessment of such testing as set forth in the Section entitled Preservation of Records Relating to Competent and Reliable Human Clinical Tests or Studies must be available for inspection and production to the Commission. Persons covered by this Section have the burden of proving that a product satisfies the definition of Essentially Equivalent Product.

III. PRESERVATION OF RECORDS RELATING TO COMPETENT AND RELIABLE HUMAN CLINICAL TESTS OR STUDIES

It is further ordered that, with regard to any human clinical test or study (“test”) upon which Defendants rely to substantiate any claim covered by this Order, Defendants must secure and preserve all underlying or supporting data and documents generally accepted by experts in the field as relevant to an assessment of the test, including:

A. All protocols and protocol amendments, reports, articles, write-ups, or other accounts of the results of the test, and drafts of such documents reviewed by the test sponsor or any other person not employed by the research entity;

B. All documents referring or relating to recruitment; randomization; instructions, including oral instructions, to participants; and participant compliance;

C. Documents sufficient to identify all test participants, including any participants who did not complete the test, and all communications with any participants relating to the test; all raw data collected from participants enrolled in the test, including any participants who did not complete the test; source documents for such data; any data dictionaries; and any case report forms;

D. All documents referring or relating to any statistical analysis of any test data, including any pretest analysis, intent-to-treat analysis, or between-group analysis performed on any test data; and

E. All documents referring or relating to the sponsorship of the test, including all communications and contracts between any sponsor and the test's researchers.

Provided, however, the preceding preservation requirement does not apply to a reliably reported test, unless the test was conducted, controlled, or sponsored, in whole or in part by: (1) any Defendant; (2) any Defendant's officers, agents, representatives, or employees; (3) any other person or entity in active concert or participation with any Defendant; (4) any person or entity affiliated with or acting on behalf of any Defendant; (5) any supplier of any ingredient contained in the product at issue to any of the foregoing or to the product's manufacturer; or (6) the supplier or manufacturer of such product.

For purposes of this Section, “reliably reported test” means a report of the test has been published in a peer-reviewed journal, and such published report provides sufficient information about the test for experts in the relevant field to assess the reliability of the results.

For any test conducted, controlled, or sponsored, in whole or in part, by any Defendant, such Defendant must establish and maintain reasonable procedures to protect the confidentiality, security, and integrity of any personal information collected from or about participants. These procedures must be documented in writing and must contain administrative, technical, and physical safeguards appropriate to Corporate Defendants’ size and complexity, the nature and scope of Defendants’ activities, and the sensitivity of the personal information collected from or about the participants.

V. FDA-APPROVED CLAIMS

It is further ordered that nothing in this Order prohibits Defendants, Defendants’ officers, agents, employees, and attorneys, or all other persons in active concert or participation with any of them from:

A. For any Drug product, making a representation that is approved for inclusion in labeling for such Drug product under a new drug application or biologics license application approved by the Food and Drug Administration, or, for any nonprescription Drug product authorized by Section 505G of the Food, Drug, and Cosmetics Act, 21 U.S.C. § 355h (“FDCA”), to be marketed

without an approved new drug application, making a representation that is permitted or required to appear in its labeling in accordance with Section 505G(a)(1)–(3) of the FDCA, 21 U.S.C. § 355h(a)(1)–(3), or a final administrative order under Section 505G(b) of the FDCA, 21 U.S.C. § 355h(b); and

B. For any product, making a representation that is specifically authorized for use in labeling for such product by regulations promulgated by the Food and Drug Administration pursuant to the Nutrition Labeling and Education Act of 1990 or permitted under Sections 303–304 of the Food and Drug Administration Modernization Act of 1997.

VI. PROHIBITED MISREPRESENTATIONS: ENDORSEMENTS

It is further ordered that Defendants, Defendants’ officers, agents, employees, and attorneys, and all other persons in active concert or participation with any of them, who receive actual notice of this Order, whether acting directly or indirectly, in connection with the advertising, marketing, promotion, offering for sale, sale, or distribution of any good or service, are permanently restrained and enjoined from misrepresenting or assisting others in misrepresenting, expressly or by implication, (1) the status of any endorser or person providing a review of the good or service, including a misrepresentation that the endorser or reviewer is an independent or ordinary

user of the good or service, or (2) that any person or organization has endorsed any good or service.

VII. JUDGMENT FOR MONETARY RELIEF

It is further ordered that judgment in the amount of Seven Million, One Hundred Forty-Six Thousand, Forty-Six Dollars (\$7,146,046) is entered in favor of Plaintiff against Individual Defendant and Corporate Defendants, jointly and severally, as monetary relief.

VIII. JUDGMENT FOR CIVIL PENALTY

It is further ordered that judgment in the amount of Five Hundred Thousand Dollars (\$500,000) is entered in favor of Plaintiff against Individual Defendant and Corporate Defendants, jointly and severally, as a civil penalty.

IX. ADDITIONAL MONETARY PROVISIONS

It is further ordered that:

A. Defendants relinquish dominion and all legal and equitable right, title, and interest in all assets transferred pursuant to this Order and may not seek the return of any assets.

B. The facts alleged in the Complaint will be taken as true, without further proof, in any subsequent civil litigation by or on behalf of the Commission, including in a proceeding to enforce its rights to any payment or monetary judgment pursuant to this Order, such as a nondischargeability complaint in any bankruptcy case.

C. The facts alleged in the Complaint establish all elements necessary to sustain an action by the Commission pursuant to Section 523(a)(2)(A) of the Bankruptcy Code, 11 U.S.C. § 523(a)(2)(A), and this Order will have collateral estoppel effect for such purposes.

D. Defendants agree that the civil penalty judgment represents a civil penalty owed to the government of the United States, is not compensation for actual pecuniary loss, and therefore, as to Individual Defendant, it is not subject to discharge under the Bankruptcy Code pursuant to 11 U.S.C. § 523(a)(7).

E. Defendants acknowledge that their Taxpayer Identification Numbers (Social Security Numbers or Employer Identification Numbers), which Defendants must submit to the Commission, may be used for collecting and reporting on any delinquent amount arising out of this Order, in accordance with 31 U.S.C. §7701.

F. All money received by the Commission pursuant to this Order may be deposited into a fund administered by the Commission or its designee to be used for consumer relief, such as redress and any attendant expenses for the administration of any redress fund. If a representative of the Commission decides that direct redress to consumers is wholly or partially impracticable or money remains after such redress is completed, the Commission may apply any remaining money for such related relief (including consumer information

remedies) as it determines to be reasonably related to Defendants' practices alleged in the Complaint. Any money not used for relief is to be deposited to the U.S. Treasury as an additional civil penalty. Defendants have no right to challenge any actions the Commission or its representatives may take pursuant to this Subsection.

X. CUSTOMER INFORMATION

It is further ordered that Defendants, Defendants' officers, agents, employees, and attorneys, and all other persons in active concert or participation with any of them, who receive actual notice of this Order, whether acting directly or indirectly, in connection with the advertising, marketing, promotion, offering for sale, sale, or distribution of any good or service, are permanently restrained and enjoined from directly or indirectly:

A. failing to provide sufficient customer information to enable the Commission to efficiently administer consumer redress. If a representative of the Commission requests in writing any information related to redress, Defendants must provide it, in the form prescribed by the Commission, within 14 days.

B. disclosing, using, or benefitting from customer information, including the name, address, telephone number, email address, social security number, other identifying information, or any data that enables access to a

customer's account (including a credit card, bank account, or other financial account), that any Defendant obtained prior to entry of this Order; and

C. failing to destroy such customer information in all forms in their possession, custody, or control within 30 days after entry of this Order.

Provided, however, that customer information need not be disposed of, and may be disclosed, to the extent requested by a government agency or required by law, regulation, or court order.

XI. ORDER ACKNOWLEDGMENTS

It is further ordered that Defendants obtain acknowledgments of receipt of this Order:

A. Each Defendant, within 7 days of entry of this Order, must submit to the Commission an acknowledgment of receipt of this Order sworn under penalty of perjury.

B. For 5 years after entry of this Order, Individual Defendant, for any business that Individual Defendant, individually or collectively with any other Defendant, is the majority owner or controls directly or indirectly, and each Corporate Defendant must deliver a copy of this Order to: (1) all principals, officers, directors, and LLC managers and members; (2) all employees having managerial responsibilities for conduct related to the subject matter of the Order and all agents and representatives who participate in conduct related to the subject matter of the Order; and (3) any business entity resulting from any

change in structure as set forth in the Section titled Compliance Reporting. Delivery must occur within 7 days of entry of this Order for current personnel. For all others, delivery must occur before they assume their responsibilities.

C. From each individual or entity to which a Defendant delivered a copy of this Order, that Defendant must obtain, within 30 days, a signed and dated acknowledgment of receipt of this Order.

XII. COMPLIANCE REPORTING

It is further ordered that Defendants make timely submissions to the Commission:

A. One year after entry of this Order, each Defendant must submit a compliance report, sworn under penalty of perjury:

1. Each Defendant must: (a) identify the primary physical, postal, and email address and telephone number, as designated points of contact, which representatives of the Commission and Plaintiff may use to communicate with Defendant; (b) identify all of that Defendant's businesses by all of their names, telephone numbers, and physical, postal, email, and Internet addresses; (c) describe the activities of each business, including the goods and services offered, the means of advertising, marketing, and sales, and the involvement of any other Defendant (which Individual Defendant must describe if they know or should know due to their own involvement); (d) describe in detail

whether and how that Defendant is in compliance with each Section of this Order; and (e) provide a copy of each Order Acknowledgment obtained pursuant to this Order, unless previously submitted to the Commission.

2. Additionally, Individual Defendant must: (a) identify all telephone numbers and all physical, postal, email and Internet addresses, including all residences; (b) identify all business activities, including any business for which Individual Defendant performs services whether as an employee or otherwise and any entity in which Individual Defendant has any ownership interest; and (c) describe in detail Individual Defendant's involvement in each such business, including title, role, responsibilities, participation, authority, control, and any ownership.

B. For 20 years after entry of this Order, each Defendant must submit a compliance notice, sworn under penalty of perjury, within 14 days of any change in the following:

1. Each Defendant must report any change in: (a) any designated point of contact; or (b) the structure of any Corporate Defendant or any entity that Defendant has any ownership interest in or controls directly or indirectly that may affect compliance obligations arising under this Order, including: creation, merger, sale, or dissolution

of the entity or any subsidiary, parent, or affiliate that engages in any acts or practices subject to this Order.

2. Additionally, each Individual Defendant must report any change in: (a) name, including aliases or fictitious name, or residence address; or (b) title or role in any business activity, including any business for which such Defendant performs services whether as an employee or otherwise and any entity in which such Defendant has any ownership interest, and identify the name, physical address, and any Internet address of the business or entity.

C. Each Defendant must submit to the Commission notice of the filing of any bankruptcy petition, insolvency proceeding, or similar proceeding by or against such Defendant within 14 days of its filing.

D. Any submission to the Commission required by this Order to be sworn under penalty of perjury must be true and accurate and comply with 28 U.S.C. § 1746, such as by concluding: “I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct. Executed on: _____” and supplying the date, signatory’s full name, title (if applicable), and signature.

E. Unless otherwise directed by a Commission representative in writing, all submissions to the Commission pursuant to this Order must be emailed to DEbrief@ftc.gov or sent by overnight courier (not the U.S. Postal

Service) to: Associate Director for Enforcement, Bureau of Consumer Protection, Federal Trade Commission, 600 Pennsylvania Avenue NW, Washington, DC 20580. The subject line must begin: United States of America v. Connors (No. [-]).

XIII. RECORDKEEPING

It is further ordered that Defendants must create certain records for 20 years after entry of the Order, and retain each such record for 5 years. Specifically, each Corporate Defendant and Individual Defendant, for any business that such Defendant, individually or collectively with any other Defendants, is a majority owner or controls directly or indirectly, must create and retain the following records:

A. accounting records showing the revenues from all goods or services sold;

B. personnel records showing, for each person providing services, whether as an employee or otherwise, that person's: name; addresses; telephone numbers; job title or position; dates of service; and (if applicable) the reason for termination;

C. records of all consumer complaints and refund requests, whether received directly or indirectly, such as through a third party, and any response;

D. all records necessary to demonstrate full compliance with each provision of this Order, including all submissions to the Commission; and

- E. a copy of each unique advertisement or other marketing material.

XIV. COMPLIANCE MONITORING

It is further ordered that, for the purpose of monitoring Defendants' compliance with this Order, including any failure to transfer any assets as required by this Order:

A. Within 14 days of receipt of a written request from a representative of the Commission or Plaintiff, each Defendant must: submit additional compliance reports or other requested information, which must be sworn under penalty of perjury; appear for depositions; and produce documents for inspection and copying. The Commission and Plaintiff are also authorized to obtain discovery, without further leave of court, using any of the procedures prescribed by Federal Rules of Civil Procedure 29, 30 (including telephonic depositions), 31, 33, 34, 36, 45, and 69.

B. For matters concerning this Order, the Commission and Plaintiff are authorized to communicate directly with each Defendant. Defendant must permit representatives of the Commission and Plaintiff to interview any employee or other person affiliated with any Defendant who has agreed to such an interview. The person interviewed may have counsel present.

C. The Commission and Plaintiff may use all other lawful means, including posing, through its representatives, as consumers, suppliers, or other individuals or entities, to Defendants or any individual or entity affiliated with

Defendants, without the necessity of identification or prior notice. Nothing in this Order limits the Commission's lawful use of compulsory process, pursuant to Sections 9 and 20 of the FTC Act, 15 U.S.C. §§ 49, 57b-1.

D. Upon written request from a representative of the Commission or Plaintiff, any consumer reporting agency must furnish consumer reports concerning Individual Defendant, pursuant to Section 604(1) of the Fair Credit Reporting Act, 15 U.S.C. §1681b(a)(1).

XV. RETENTION OF JURISDICTION

It is further ordered that this Court retains jurisdiction of this matter for purposes of construction, modification, and enforcement of this Order.

DONE and **ORDERED** in Fort Myers, Florida on July 26, 2023.


SHERI POLSTER CHAPPELL
UNITED STATES DISTRICT JUDGE

Copies: All Parties of Record